K 111 632

Page 1 of (2)

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Pinnacle Spine Group, LLC
DATE PREPARED:	June 09, 2011
CONTACT PERSON:	Rebecca K Pine 1601 Elm Street, Suite 300 Dallas, TX 75201 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	InFill™ Graft Delivery System
CLASSIFICATION NAME:	Piston Syringe
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	880.5860
PRODUCT CODE	FMF
PREDICATE DEVICES:	Wright Medical Bone Graft Syringe, K023088 FibirJet Graft Delivery System K100754

Substantially Equivalent To:
The InFill™ Graft Delivery System is substantially equivalent in intended use, principal of operation and technological characteristics to the Wright Medical Bone Graft Delivery System and the FibriJet Graft Delivery System.

Description of the Device Subject to Premarket Notification:
The InFill™ Graft Delivery System is comprised of a commercially available disposable medical piston syringe (syringe barrel w/female luer, plunger) and a cannulated applicator tip. The InFill™ Graft Delivery System is provided sterile, for single use only.

Indication for Use:
The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site.

Technological Characteristics:
The InFill™ Graft Delivery System has the same technological characteristics and is

similar in overall design, materials and configuration compared to the predicates.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, the InFill™ Graft Delivery System is determined by Pinnacle Spine Group, LLC, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pinnacle Spine Group, LLC
% Ms. Rebecca K. Pine
1601 Elm Street, Suite 300
Dallas, Texas 75201

Re: K111632
Trade/Device Name: InFill™ Graft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 09, 2011
Received: June 13, 2011

AUG 1 1 2011

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111632

Device Name: **InFill™ Graft Delivery System**

Indications for Use:

The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use __X__
(Per 21 CFR 801.109)

Over-The-Counter Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111632